
		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

1) Test Name: Description Visual examination				
No Data Transfer Methods are configured				
Procedure Taken 10 (about 10) Empty Hard Gelatin Capsules shells in clean and dry petridish and observed.				
Q1	Size # 1; Cap: Buff and Body: Buff, printed "IP 102" on CAP and BODY.			
Q2	Does not comply			
Observation: (EWS001__TA654) :Q1				
Observed Quality: Size # 1; Cap: Buff and Body: Buff, printed "IP 102" on CAP and BODY. Pass Limit Description: Size # 1; Cap: Buff and Body: Buff, printed "IP 102" on CAP and BODY. Result: Pass				
1	Analysed By	Dishant. Joshi	18-Jan-2024 14:55	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
2) Test Name: Capsule colour				
No Data Transfer Methods are configured				
Procedure Placed a sample and the corresponding approved specimen of Empty Hard Gelatin Capsule Shells side by side. Compared both under natural light from a distance of 25 cm.				
Remarks: Color Shade Refer no.: -E0925/2013				
Q1	Complies			
Q2	Does not comply			
Observation: (EWS001__TB218) :Q1				
Observed Quality: Complies Pass Limit Description: As per approved colour shade. Result: Pass				
1	Analysed By	Dishant. Joshi	18-Jan-2024 14:57	---
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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

3) Test Name: Identification of Gelatin			
Instrument ID	QC/EQ/725	Instrument Name	Analytical Balance
Calibrated On	18-Jan-2024 10:50	Next Calibration Date	05-Feb-2024 00:00
Instrument Usage Code	8025696	Used By	Nidhi.Prajapati
Used From	20-Jan-2024 10:16	Used Upto	20-Jan-2024 10:18
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight of Sample(EDAP001__WA772)	1.03835	

Work Sheet Fields			
W.S. Field: Chemical - 01, W.S. Value: N/A (By-Passed), Comments: N/A			
W.S. Field: Chemical - 02, W.S. Value: N/A (By-Passed), Comments: N/A			
Instrument (Instrument ID):Water Bath(QC/EQ/697)			
Calibrated On	01-Feb-2023	Calibration Due Date	19-Feb-2024
Used From	20-Jan-2024 08:38	Used UpTo	20-Jan-2024 12:44
Other Information: Used For: ID of gelatin ,Sample Reference No.: AN01RME24000037, W.S. Field: Instrument - 01, W.S. Value: 8025934 (Existing Usage), Comments: --			
W.S. Field: Instrument - 02, W.S. Value: N/A (By-Passed), Comments: N/A			
W.S. Field: Instrument - 03, W.S. Value: N/A (By-Passed), Comments: N/A			
W.S. Field: Instrument - 04, W.S. Value: N/A (By-Passed), Comments: N/A			
W.S. Field: Instrument - 05, W.S. Value: N/A (By-Passed), Comments: N/A			
W.S. Field: Instrument - 06, W.S. Value: N/A (By-Passed), Comments: N/A			
Solution Name:3N Hydrochloric Acid			
Solution Type	Reagents/Indicators	Preparation No.	RI00010/240012
Solution Expiry Date	20-Jan-2024	Used On	20-Jan-2024
Other Information: Sample Reference No.: AN01RME24000041, W.S. Field: Test Solution - 01, W.S. Value: RI00010/240012/0003 (New Usage), Comments: --			
W.S. Field: Test Solution - 02, W.S. Value: N/A (By-Passed), Comments: N/A			
Chemical / Reagent Name:Potassium dichromate_Rankem_AR_500 g			
Chemical / Reagent Issue	AN01CH0033921001/005	Batch No.	J182A21

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	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

No.			
Valid Upto	16-Jan-2026	Qty. Value	11.8 g
Other Information: Sample Reference No.: AN01RME24000037 , W.S. Field: WSF_CHM_ID001 , W.S. Value: AN01CH0033921001/005/0046(Existing Usage) , Comments: --			

Preparation of Solutions

0.2 M Potassium Dichromate

Weighed accurately **11.80 g (about 11.77 g)** Potassium Dichromate and transferred into a **200 mL (200 mL)** volumetric flask. Added **100 mL (about 100 mL)** of water and dissolved the powder completely, Diluted to volume with water.

0.2 M Potassium Dichromate and 3 N hydrochloric Acid mixture (4:1)


Prepared a mixture of **200 mL (200 mL)** of 0.2 M potassium dichromate and **50 mL (50 mL)** of 3 N Hydrochloric acid. Mixed well.

Sample Preparation

Weighed **1.03835 g (about 1 g)** of capsules into a suitable container. Added **100 mL (100 mL)** of water. Covered the sample container and heated on a water bath at **65°C ± 2°C** until the capsule shells are dissolved.

Start Time: **10:30** Temperature: **65.0 °C**

End Time: **11:00** Temperature: **65.0 °C**

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RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Procedure

Taken **10 mL (10 mL)** of the sample solution; added **2 mL (2 mL)** of the 0.2 M potassium dichromate and 3 N hydrochloric acid mixtures (4:1). Examined the sample solution for the formation of yellow precipitate.

Observation: *A yellow precipitate is formed.*

For Individual container

Performed the Identification test of individual container (as applicable). Weight recorded in test "**Identification_ Weight for container**" and followed same test procedure as mentioned above.

No. of Container : **7**


Observation for Container No. Composite	: <i>A yellow precipitate is formed.</i>
Observation for Container No. 8/80	: <i>A yellow precipitate is formed.</i>
Observation for Container No. 28/80	: <i>A yellow precipitate is formed.</i>
Observation for Container No. 30/80	: <i>A yellow precipitate is formed.</i>
Observation for Container No. 32/80	: <i>A yellow precipitate is formed.</i>
Observation for Container No. 73/80	: <i>A yellow precipitate is formed.</i>
Observation for Container No. 75/80	: <i>A yellow precipitate is formed.</i>
Observation for Container No. 77/80	: <i>A yellow precipitate is formed.</i>
Observation for Container No. N/A	: <i>N/A</i>
Observation for Container No. N/A	: <i>N/A</i>

Verification of Container No.: From **Composite** to **77/80**


Verified By: *Sujeet Rai (AR01430)*

Observation for Container No. **N/A** : *N/A*

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	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Verification of Container No.: From <i>N/A</i> to <i>N/A</i>	
Verified By: <i>N/A</i>	
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Verification of Container No.: From <i>N/A</i> to <i>N/A</i>	
Verified By: <i>N/A</i>	
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>

	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Observation for Container No. <i>N/A</i>	: <i>N/A</i>
Verification of Container No.: From <i>N/A</i> to <i>N/A</i> Verified By: <i>N/A</i>	
Remarks: <i>N/A</i>	


Q1	A yellow precipitate is formed.
Q2	Does not comply
Observation: (EWS001__TA772) :Q1	

Observed Quality: A yellow precipitate is formed. Pass Limit Description: A yellow precipitate is formed Result: Pass
--

1	Analysed By	Nidhi. Prajapati	20-Jan-2024 14:29	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

4) Test Name: Identification_Weight for container			
Instrument ID	QC/EQ/725	Instrument Name	Analytical Balance
Calibrated On	18-Jan-2024 10:50	Next Calibration Date	05-Feb-2024 00:00
Instrument Usage Code	8025705	Used By	Nidhi.Prajapati
Used From	20-Jan-2024 10:18	Used Upto	20-Jan-2024 10:25
Mode	Inst. Conn.	Reasons	
S.No.	Field Desc.	Field Value	
1	Weight of container(g)(EDAP001__TF194)	1.03673,1.02687,1.01646,1.03518,1.01995,1.02684,1.03298	

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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Remarks: *N/A*

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	Weight of container	A	EDAP001__TF194	1.03673,1.02687,1.01646,1.03518,1.01995,1.02684,1.03298g

Set-1			
S. No.	Variable (Symbol)	Value	UOM
1	Weight of container (A)	1.03673	g
	Weight of container-1 (A) =	1.03673	g

Set-2			
S. No.	Variable (Symbol)	Value	UOM
1	Weight of container (A)	1.02687	g
	Weight of container-2 (A) =	1.02687	g

Set-3			
S. No.	Variable (Symbol)	Value	UOM
1	Weight of container (A)	1.01646	g
	Weight of container-3 (A) =	1.01646	g


Set-4			
S. No.	Variable (Symbol)	Value	UOM
1	Weight of container (A)	1.03518	g
	Weight of container-4 (A) =	1.03518	g

Set-5			
S. No.	Variable (Symbol)	Value	UOM
1	Weight of container (A)	1.01995	g
	Weight of container-5 (A) =	1.01995	g


Set-6			
S. No.	Variable (Symbol)	Value	UOM
1	Weight of container (A)	1.02684	g
	Weight of container-6 (A) =	1.02684	g

Set-7			
S. No.	Variable (Symbol)	Value	UOM
1	Weight of container (A)	1.03298	g
	Weight of container-7 (A) =	1.03298	g

S. No.	Variable Reading	Value	UOM
1	Weight of container-1	1.03673	g
2	Weight of container-2	1.02687	g
3	Weight of container-3	1.01646	g
4	Weight of container-4	1.03518	g
5	Weight of container-5	1.01995	g
6	Weight of container-6	1.02684	g
7	Weight of container-7	1.03298	g

		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
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Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

No. Of Decimals: 5				
S. No.	Calculated Value		Limit	Result
1	Minimum: 1.01646 g		0.00000	Pass
Pass Limits(s): Should be comply Final Result: Pass				
1	Analysed By	Nidhi. Prajapati	20-Jan-2024 10:26	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
5) Test Name: *Identification of Iron Oxide				
No Data Transfer Methods are configured				
Result to be transcribed from Vendor COA				
Remarks: N/A				
Q1	Complies			
Q2	Does not comply			
Observation: (EWS001__TBP23) :Q1				
Observed Quality: Complies Pass Limit Description: Conforms to composition Result: Pass				
1	Analysed By	Mansi. Vyas	13-Jan-2024 15:54	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
6) Test Name: *Identification of Titanium Dioxide				
No Data Transfer Methods are configured				
Result to be transcribed from Vendor COA				
Remarks: N/A				
Q1	Complies			
Q2	Does not comply			
Observation: (EWS001__TBP24) :Q1				
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	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
RAW DATA SHEET (Raw Material (Excipient))			
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Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Observed Quality: [Complies](#)

Pass Limit Description: Pale yellow to dark yellow orange color produced.

Result: [Pass](#)

1	Analysed By	Mansi. Vyas	13-Jan-2024 15:54	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

7) Test Name: *Disintegration Time

No Data Transfer Methods are configured

Result to be transcribed from Vendor COA

Remarks: [N/A](#)

Q1	Less than 15:00 minutes
Q2	Does not comply
Special Observation: (EWS002__TBP25) : 3 minutes	
Pass / Fail Status: (of Special Observation)(EWS003__TBP25) : Pass	

Observed Quality: [3 minutes](#)

Pass Limit Description: Not more than 15:00 minutes.

Result: [Pass](#)

1	Analysed By	Mansi. Vyas	13-Jan-2024 15:55	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

8) Test Name: *Loss on Drying

No Data Transfer Methods are configured


Result to be transcribed from Vendor COA

Remarks: [N/A](#)

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	Loss on Drying	A	EWS007__TBP26	15.4%

Formula: (A)

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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
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Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04	
Amneal Receiving No.	23013081	GRN No.	CRM 23008709	

UOM (R): %
No. Of Decimals: 1
Calculated Value: 15.4 %
Pass Limit Description: Not less than 13.0 % and Not more than 16.0 %.
Result: Pass

1	Analysed By	Mansi. Vyas	13-Jan-2024 15:56	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

9) Test Name: *Average Weight

No Data Transfer Methods are configured
Result to be transcribed from Vendor COA

Remarks: N/A

S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
1	Average Weight	A	EWS001_TBP27	79.4mg

Formula: (A)
UOM (R): mg
No. Of Decimals: 1
Calculated Value: 79.4 mg
Pass Limit Description: 76.0 - 81.0 mg
Result: Pass

1	Analysed By	Mansi. Vyas	13-Jan-2024 15:56	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---


10) Test Name: *Odour

No Data Transfer Methods are configured
Result to be transcribed from Vendor COA


Remarks: N/A

Q1	Complies
Q2	Does not comply


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Note : This document has been generated electronically and is valid without signature.		
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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
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Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Observation: (EWS001__TBP28) :Q1				
Observed Quality: Complies Pass Limit Description: No foreign odour Result: Pass				
1	Analysed By	Mansi. Vyas	13-Jan-2024 15:56	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
11) Test Name: *Sulphated Ash				
No Data Transfer Methods are configured Result to be transcribed from Vendor COA Remarks: N/A				
Q1	Less than 7 %			
Q2	Complies			
Q3	Does not comply			
Observation: (EWS001__TBP29) :Q2				
Observed Quality: Complies Pass Limit Description: Not more than 7 % Result: Pass				
1	Analysed By	Mansi. Vyas	13-Jan-2024 15:57	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
12) Test Name: *Lubricant content				
No Data Transfer Methods are configured Result to be transcribed from Vendor COA Remarks: N/A				
Q1	Less than 0.5 %.			
Q2	Complies			
Q3	Does not comply			
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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Observation: (EWS001__TBP30) :Q2				
Observed Quality: Complies Pass Limit Description: Not more than 0.5 %. Result: Pass				
1	Analysed By	Mansi. Vyas	13-Jan-2024 15:58	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
13) Test Name: *Sulphur Dioxide				
No Data Transfer Methods are configured Result to be transcribed from Vendor COA Remarks: N/A				
Q1	Less than 50 ppm			
Q2	Complies			
Q3	Does not comply			
Observation: (EWS001__TBP31) :Q2				
Observed Quality: Complies Pass Limit Description: Not more than 50 ppm Result: Pass				
1	Analysed By	Mansi. Vyas	13-Jan-2024 15:58	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
14) Test Name: *Arsenic By ICPMS				
No Data Transfer Methods are configured Result to be transcribed from Vendor COA Remarks: N/A				
Q1	Less than 1 ppm			
Q2	Complies			
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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Q3	Does not comply		
Observation: (EWS001__TBP32) :Q2			
Observed Quality: Complies Pass Limit Description: Not more than 1 ppm Result: Pass			
1	Analysed By	Mansi. Vyas	13-Jan-2024 15:59
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10
4	Accepted By	Amol.Charde	25-Jan-2024 13:07
15) Test Name: *Lead By ICPMS			
No Data Transfer Methods are configured			
Result to be transcribed from Vendor COA			
Remarks: N/A			
Q1	Less than 1 ppm		
Q2	Complies		
Q3	Does not comply		
Observation: (EWS001__TBP33) :Q2			
Observed Quality: Complies Pass Limit Description: Not more than 1 ppm Result: Pass			
1	Analysed By	Mansi. Vyas	13-Jan-2024 16:00
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10
4	Accepted By	Amol.Charde	25-Jan-2024 13:07
16) Test Name: *Cadmium By ICPMS			
No Data Transfer Methods are configured			
Result to be transcribed from Vendor COA			
Remarks: N/A			

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Note : This document has been generated electronically and is valid without signature.		
Format No. N/A		

	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Q1	Less than 0.5 ppm
Q2	Complies
Q3	Does not comply
Observation: (EWS001__TBP34) :Q2	

Observed Quality: [Complies](#)

Pass Limit Description: Not more than 0.5 ppm

Result: [Pass](#)

1	Analysed By	Mansi. Vyas	13-Jan-2024 16:00	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

17) Test Name: *Mercury
By ICPMS

No Data Transfer Methods are configured

Result to be transcribed from Vendor COA

Remarks: [N/A](#)

Q1	Less than 0.1 ppm
Q2	Complies
Q3	Does not comply
Observation: (EWS001__TBP35) :Q2	

Observed Quality: [Complies](#)

Pass Limit Description: Not more than 0.1 ppm


Result: [Pass](#)

1	Analysed By	Mansi. Vyas	13-Jan-2024 16:01	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---


18) Test Name: *Microbial enumeration tests (USP<61>)(Group Name: Microbial enumeration tests (USP<61>) and Tests for Specified Microorganisms (USP<62>))

No Data Transfer Methods are configured


Result to be transcribed from Vendor COA

		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Remarks: N/A				
Sub Test-1: Total bacterial count				
Q1	Complies			
Q2	Does not comply			
Special Observation: (EWS002__TBP36) :10 cfu/g				
Pass / Fail Status: (of Special Observation)(EWS003__TBP36) :Pass				
Observed Quality: 10 cfu/g Pass Limit Description: Not more than 500 cfu/g Result: Pass				
Sub Test-2: Total yeasts and molds count				
Q1	Complies			
Q2	Does not comply			
Special Observation: (EWS005__TBP36) :<10 cfu/g				
Pass / Fail Status: (of Special Observation)(EWS006__TBP36) :Pass				
Observed Quality: <10 cfu/g Pass Limit Description: Not more than 100 cfu/g Result: Pass Final Result: Pass				
1	Analysed By	Mansi. Vyas	13-Jan-2024 16:02	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
19) Test Name: *Tests for Specified Microorganisms (USP<62>)(Group Name: Microbial enumeration tests (USP<61>) and Tests for Specified Microorganisms (USP<62>))				
No Data Transfer Methods are configured				
Result to be transcribed from Vendor COA				
Remarks: N/A				
Sub Test-1: Escherichia coli				
Q1	Absent			
Q2	Present			
Observation: (EWS001__TBP37) :Q1				
Observed Quality: Absent Pass Limit Description: Absent / 1g				
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	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Result: Pass Sub Test-2: Salmonella				
Q1	Absent			
Q2	Present			
Observation: (EWS004__TBP37) :Q1				
Observed Quality: Absent Pass Limit Description: Absent / 10g Result: Pass Sub Test-3: Pseudomonas aeruginosa				
Q1	Absent			
Q2	Present			
Observation: (EWS007__TBP37) :Q1				
Observed Quality: Absent Pass Limit Description: Absent / 1g Result: Pass Sub Test-4: Staphylococcus aureus				
Q1	Absent			
Q2	Present			
Observation: (EWS010__TBP37) :Q1				
Observed Quality: Absent Pass Limit Description: Absent / 1g Result: Pass Final Result: Pass				
1	Analysed By	Mansi. Vyas	13-Jan-2024 16:03	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---
20) Test Name: *Capsule Joined Length				
No Data Transfer Methods are configured				
Result to be transcribed from Vendor COA				
Remarks: N/A				
S. No.	Variable	Symbol	TDS Symbol	Value(UOM)
Printed by: Jayesh.Prajapati				
Printed on: 29-Jan-2024 10:33			Page No.: 16 of 24	
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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

1	Capsules Joined Length	A	EWS001 TCY32	19.3mm
---	------------------------	---	--------------	--------

Formula: (A)
UOM (R): mm
No. Of Decimals: 1
Calculated Value: 19.3 mm
Pass Limit Description: 19.3 ± 0.4 mm
 (Average of 20 Capsules Joined Length)
Result: Pass

1	Analysed By	Mansi. Vyas	13-Jan-2024 16:03	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

21) Test Name: Acceptable Quality Level (AQL)

No Data Transfer Methods are configured

Work Sheet Fields

W.S. Field: Instrument - 01, W.S. Value: N/A (By-Passed), Comments: N/A

W.S. Field: Instrument - 02, W.S. Value: N/A (By-Passed), Comments: N/A

Procedure


Collect the sample as per SOP # QC-004 (Sampling of Raw Materials). For AQL following sampling plan to be used.

Sample taken 1250 NOS

Old Value:1250	Reasons:Typo graphical error	Changed By:Dishant. Joshi 18-Jan-2024 15:00:01
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Sampling Plan / AQL for Visual Defects & Print Defects

Lot Size	Sample	Visual Defects	Print defects
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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

(Units)	Size (Units)	Critical Defect		Major Defect		Minor Defect		Critical Defect		Major Defect		Minor Defect	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
Less than 500000	800	0	1	1	2	7	8	0	1	2	3	21	22
500000 and above	1250	0	1	1	2	7	8	0	1	2	3	21	22

Ac: Acceptance Number Re: Rejection number

Visual defects


Definition of Visual Defects

Critical defect	Is a defect that affects the performance of a capsule as package for the final product or contributes to a major filling problem.
Major defect	Is a defect that may cause a problem on a filling machine.
Minor defect	Is a defect that has no effect on the performance of a capsule as a package. It is a slight blemish that makes the capsule visually imperfect.

Note: Powder residue may be observed on empty hard gelatin capsule shell.


Categorization and Description of Visual Defects

CATEGORY	DESCRIPTION
Critical defects	HOLE: It is a capsule, which has been pierced on any part of its surface.
	UNCUT BODY: It is a capsule whose body has not been cut. The length becomes more by 3 to 5 mm than nominal length.
	UNCUT CAP: It is a capsule whose cap has not been cut. The length becomes more by 3 to 5mm than nominal length.
	MASHED: It is a capsule, which is totally deformed or crumpled.

	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

		TRIMS (LOOSE RING OUTSIDE): It is surplus shell from the dipping resulting from cutting of the shell. It can be from cap or body.
		TRIMS (LOOSE RING INSIDE): It is a capsule, which has loose ring inside the joined shells. It can be from cap or body.
		SPLIT (RAPID DRIED): It is a capsule having longitudinal break in film straight or spiral, form the edge of cap or body cut end. Critical defect if the cut is more than 1 mm.
		TELESCOPED: It is a capsule whose body is partially cut and come out of cap during joining.
		DOUBLE DIP: Double dip is the shell which got dipped twice, hence has high Weight, SWT, Dome etc.
		STRING ON END: It is a capsule whose either cap or body has excess gelatin in the form of string near dome.
		SHORT BODY: Length of body shorter by 2 mm than nominal length.
Major defects		PUNCHED END (DENTED): It is a capsule whose either cap or body has inverted dome. Major defect if the indentation is more than 2 mm diameter.
		COLLET PINCH: It is a capsule whose either cap or body has longitudinal pinch generated by collet. Major defect if the pinch is more than 3 mm in length.
		ROUGH CUT: It is a capsule whose either cap or body has irregular cut causing abnormal resistance for separation or causing loading problem during filling.
		LOOSE PIECE: It is a cap or bodies, which are cut to the length but are found in unjoined state.
		DOUBLE CAP: It is a joined capsule, which has two caps.
		LONG CAP/BODY: Length of cap or body longer by 1 mm than nominal length.
		SHORT CAP: Length of cap shorter by 1 mm than nominal length.
Minor defects		DIRTY: It is a capsule on which marks can be recognized at a distance of 30 cm under natural light with an area of 3 sq. mm.
		BUBBLES: It is a capsule having bubble either on cap or body having diameter more than 1 mm.
		SPECKS: It is a capsule having speck either on cap or body having diameter more than 1 mm.
		STAR END: It is a capsule whose either cap or body has top stellated wrinkles greater than 3 mm diameter.
		WRINKLES: It is a capsule whose either cap or body has longitudinal wrinkles greater than 3mm×2mm.
		UNEVEN CUT: It is a capsule whose either cap or body has uneven cut.
		STRING (SPIRAL CUT): It is a capsule whose either cap or body has a string generated due to spiral cutting at the cutting edge. Major defect if length of string

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	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

	is more than 2 mm.
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Print Defects

Definition of Print Defects

Critical defects	Missing print or complete absence of the logo
Major defect	Defect resulting in illegibility of print or non-identification of printed logo
Minor defect	Printing defects, which do not affect the legibility or identification of the printed logo but detract from the visual appearance of the capsule.

Categorization and Description of Print Defects

CATEGORY	DESCRIPTION
Critical Defect	MISSING PRINT: it is a capsule with complete absence of print matter
Major Defect	SMUDGED PRINT: Capsule with extensive smudging resulting in illegibility of print matter.
	MULTIPLE PRINTS: Capsule with print in multiple positions resulting in illegibility of the print.
	BROKEN LETTERS (CUT PRINT): Capsules with interruption in print matter-causing illegibility of print matter.
	OFF REGISTER PRINT: Capsules with letters missing resulting in non-identification of print matter.
	INK SPOT: Capsules with ink spots greater than 4 mm diameter.
Minor defects	SMUDGED PRINT: Capsule with smudging, resulting in partial illegibility of print matter.
	BROKEN LETTERS (CUT PRINT): Capsules with partial interruption in print matter but print matter remains legible.

	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

	OFF REGISTER PRINT: Capsules where registration is offset but print matter remains intact.
	INK SPOT: Capsules with ink spots between 1 mm to 4 mm diameter.
	INK LINE: Capsules with line through print matter, legibility is not affected.

Procedure of inspection of Visual Defects and Print Defects

Taken capsule as per sampling plan & spread it on inspection table. Inspect it in upper and lower light of inspection table. If the total number of defects within acceptable limits, accept the batch. If the total number of defects is equivalent to, or more than the rejection number, reject the lot. QC personnel shall inform QC in charge if problem is detected.

Visual Inspection Report

1. Visually inspect each sampled capsule shells for types of defects.
2. If the total numbers of the defects are within acceptable limits, accept the batch.
3. If the total numbers of the defects are equivalent to, or more than rejection number, reject the lot.
4. Report the result in the laboratory notebook or LIMS as applicable.


Observation

Visual Defect

Critical : 00

Major : 00

Minor : 00

	AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India		
	RAW DATA SHEET (Raw Material (Excipient))		
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

Print Defect Critical : 00 Major : 00 Minor : 00 Remarks: N/A

Q1	Complies
Q2	Does not comply
Observation: (EWS001__TV151) :Q1	


Observed Quality: Complies Pass Limit Description: Comply / Does not comply Result: Pass				
1	Analysed By	Dishant. Joshi	18-Jan-2024 15:30	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

22) Test Name: *Residual Solvent No Data Transfer Methods are configured Result to be transcribed from Vendor COA Remarks: N/A

Q1	Complies
Q2	Does not comply
Observation: (EWS001__TCY33) :Q1	

Observed Quality: Complies Pass Limit Description: Meets the requirements. Result: Pass	
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RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709


1	Analysed By	Mansi. Vyas	13-Jan-2024 16:04	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

23) Test Name: Vendor COA		
No Data Transfer Methods are configured		
Remarks: N/A		
Reference Document(s)		
S.No.	Document Code	Document Description
1	AN01RME24000041_COA	AN01RME24000041_COA
Q1	Complies	
Q2	Does not comply	
Observation: (EWS001__TF198) : Q1		
Observed Quality: Complies Pass Limit Description: The test results reported on the material Certificate of Analysis (COA) from the manufacturer / vendor, meet the manufacturer / vendor specification. Result: Pass		

1	Analysed By	Mansi. Vyas	13-Jan-2024 15:53	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---

24) Test Name: Transportation Temperature Monitoring		
No Data Transfer Methods are configured		
Remarks: N/A		
Reference Document(s)		
S.No.	Document Code	Document Description
1	AN01RME24000041_TTM	AN01RME24000041_TTM
Q1	Complies	
Q2	Does not comply	
Observation: (EWS001__TF200) : Q1		
Observed Quality: Complies Pass Limit Description: For Information Result: Pass		

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		AMNEAL PHARMACEUTICALS PVT. LTD. 882/1-871, Village Rajoda Near Hotel Kankavati, Taluka.: Bavla, Dist.: Ahmedabad-382220, State: Gujarat India	
RAW DATA SHEET (Raw Material (Excipient))			
Material Name: Empty Hard Gelatin Capsules (Buff/Buff) Size # 1(cap and body: Buff, printed "IP 102" on cap and body)			
Material Code	RM-0491	LIMS A.R. No.	AN01RME24000041
Manufacturer Lot No./Batch No.	1100243596	Specification No.	RM-0491-US-04
Amneal Receiving No.	23013081	GRN No.	CRM 23008709

1	Analysed By	Dishant. Joshi	18-Jan-2024 13:00	---
2	Accepted By	Karishma.Patel	24-Jan-2024 11:15	---
3	Accepted By	Umesh.Sheladiya	24-Jan-2024 13:10	---
4	Accepted By	Amol.Charde	25-Jan-2024 13:07	---